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EXAMINER	
ROANE, AARON F	

ART UNIT	PAPER NUMBER
3769	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/727,143	SWANSON, DAVID K.	
	Examiner	Art Unit	
	Aaron Roane	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,27-40,42-44 and 46-54* is/are pending in the application.

4a) Of the above claim(s) *7,37 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-10,27-36,39,40,42-44 and 46-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 9, 10, 27-34, 36, 39, 40, 42-44 and 47, 49-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maguire et al. (U.S. Patent 5,755,760) in view of Leob et al. (U.S. Patent 6,286,512) in further view of Dupree et al. (U.S. Patent 6,542,773).

Regarding claims 1-3, 5, 27 and 47, Maguire et al. disclose a surgical probe, comprising: a single, relatively short tubular shaft ("catheter body" 10, see col. 3:43-50 and figure 1) defining a distal region and a proximal region; a coagulation element (electrode(s) 12 and/or 16, see col. 3:43-52 and figure 1) configured to emit energy for coagulating tissue and forming a lesion within tissue, the coagulation element defining a coagulation element configuration (coil electrode(s) configuration) on the distal region of the relatively short tubular shaft; and a mapping element ("electrode" 20 and "additional mapping electrodes may optionally be added between electrodes 12 and 16 and/or proximal to electrode 12," see col. 3:45-54 and figure 1) defining a stimulation/mapping element configuration on the distal region of the same relatively short tubular shaft, the stimulation/mapping element configuration (cap electrode configuration) being different than the coagulation element configuration, see col. 3:43 – col. 4:14 in general and figure

1. Maguire et al. fail to explicitly disclose 1) that the mapping electrodes are configured to emit energy to tissue for stimulating tissue and evaluating formation of the lesion, the stimulation element and 2) a source of stimulation energy. Both Maguire et al. and Leob et al. are silent as to a source of stimulation energy, which the examiner interprets has simply a source operatively coupled to the mapping/stimulation electrodes to deliver energy to the mapping/stimulation electrodes. Leob et al. disclose an electrosurgical device and procedure for forming a channel within tissue and teach "attached to the cannula distal end portion 773 are serially spaced mapping electrode rings 715 for monitoring parts of the body. Such mapping electrodes are known in the art and, for example, provide for electrically mapping the heart by receiving and transmitting electrical signals related to the operation of that organ to recording signal processing and display devices," see col. 15:27-57 and figure 20. Leob et al. disclose that it is known in the art that mapping electrodes not only receive (i.e. sense, detect, etc.) electrical signals but also transmit (i.e. send, deliver, etc.) electrical signals. The transmission of electrical signals through tissue to by the mapping electrodes meets the function of a stimulating element. Dupree et al. disclose a device and method for mapping and ablating tissue and "the techniques used to analyze these pathways, commonly called 'mapping,' identify regions in the heart tissue, called foci, which can be ablated to treat the arrhythmia. When used for this purpose, the multiple electrode arrays are typically located in electrical contact with either epicardial or endocardial tissue. The multiple electrodes are coupled to an external cardiac stimulator, which applies electrical pacing signals through one or more electrodes at given frequencies, durations, or amplitudes to myocardial

tissue, a process called 'pacing.' The multiple electrodes on the array are also typically coupled to signal processing equipment, called 'recorders,' which display the morphologies of the electrocardiograms or electrograms recorded during pacing," see col. 1:23-36. Dupree et al. teach the pacing pulses (delivered to the mapping electrodes) are "generated by the stimulator 20" which is a subsystem of "instrument interface" 26 (i.e. the stimulation source), see col. 8:54-57 and figure 2. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Maguire et al., as taught by Leob et al., to use mapping electrodes, as is known in the art, that both stimulate tissue (transmit electrical signals through tissue) and receive electrical signals (stimuli) in order to map the tissue, as further taught by Dupree et al., to provide the system with a source of stimulation energy operatively coupled to the stimulation/mapping electrodes in order to map the tissue treatment area. **Finally, the recitation of "supplying tissue stimulation energy to a first side of a lesion that is formed as a result of ablating tissue such that a second side of the lesion can be monitored to determine a depth of the lesion" is a recitation of 1) intended use, 2) language directed to how the device/element is intended to be employed and/or 3) a functional limitation. A recitation of intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. However, if a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. A recitation with respect to**

the manner in which an apparatus is intended to be employed does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim. In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974); In re Yanush, 477 F.2d 958, 177 USPQ 705 (CCPA 1973); In re Finsterwalder, 436 F.2d 1028, 168 USPQ 530 (CCPA 1971); In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 136 USPQ 458 (CCPA 1963); Ex parte Masham, 2 USPQ2d 1647 (BdPatApp & Inter 1987). It is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, *i.e.*, a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim. In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974); In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 136 USPQ 458 (CCPA 1963). Where the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function. In re Ludtke, 441 F.2d 660, 169 USPQ 563 (CCPA 1971). In addition, where there is reason to believe that such functional limitation may be an inherent characteristic of the prior art reference, Applicant is required to prove that the subject matter shown in the prior art reference does not possess the characteristic relied upon. In re Spada, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990); In re King, 801 F.2d 1324,

1327, 231 USPQ 136, 138 (Fed. Cir. 1986); In re Ludtke, 441 F.2d at 664, 169 USPQ at 566 (CCPA 1971).

Regarding claim 6, Maguire et al. further disclose at least two longitudinally spaced coagulation electrodes (electrodes 12 and 16, see col. 3:43-52 and figure 1) having a size and spacing. The recitation of "the at least two coagulation electrodes being such that simultaneous transmission of energy thereby to an indifferent electrode will produce an area of coagulated tissue that spans the at least two coagulation electrodes" is intended use. A recitation of intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. However, if a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. Furthermore, the entire disclosure of Maguire et al. is directed to creating elongated lesions.

Regarding claim 9, Maguire et al. further disclose a handle ("control handle" 22, see col. 3:54-60 and figure 1) associated with the proximal region of the relatively short tubular shaft.

Regarding claim 10, Maguire et al. in view of Leob et al. disclose the stimulation element, in the form of a mapping electrode (20 of Maguire et al. figures 1 and 3) is

located distally of the coagulation element, in the form of ablation/coagulation electrodes 12 and 16, see col. 3:43-52 and figures 1 and 3).

Regarding claim 28, Maguire et al. in view of Leob et al. in further view of Dupree et al. disclose the claimed invention. In particular, Maguire et al. alone disclose coagulation energy lines (104 and 102, see col. 5:8-19 and figure 3) connected to the coagulation elements (12 and 16 respectively) and a coagulation energy connectors (proximal ends of 104 and 102 respectively) and a stimulation energy line (118, see col. 5:20-38 and figure 3) connected to the stimulation element (20) and a stimulation energy connector (proximal end of 118). It should be noted the coagulation energy connectors (proximal ends of 104 and 102 respectively) and the stimulation energy connector (proximal end of 118) are located within "electrical connector "28", see col. 3:63-65 and figure 1. Additionally, that recitation that the coagulation line and stimulation line are configured to be connected to the coagulation source and stimulation source respectively is intended use, a functional limitation and/or intended to be employed. A recitation of intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. However, if a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. It is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, *i.e.*, a functional limitation, does not impose any structural limitation

upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim. In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974); In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 136 USPQ 458 (CCPA 1963). Where the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function. In re Ludtke, 441 F.2d 660, 169 USPQ 563 (CCPA 1971). In addition, where there is reason to believe that such functional limitation may be an inherent characteristic of the prior art reference, Applicant is required to prove that the subject matter shown in the prior art reference does not possess the characteristic relied upon. In re Spada, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990); In re King, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986); In re Ludtke, 441 F.2d at 664, 169 USPQ at 566 (CCPA 1971). A recitation with respect to the manner in which an apparatus is intended to be employed does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim. In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974); In re Yanush, 477 F.2d 958, 177 USPQ 705 (CCPA 1973); In re Finsterwalder, 436 F.2d 1028, 168 USPQ 530 (CCPA 1971); In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 136 USPQ 458 (CCPA 1963); Ex parte Masham, 2 USPQ2d 1647 (BdPatApp & Inter 1987). Finally and most importantly Dupree et al.

clearly disclose a coagulation line connected to a coagulation source and a stimulation line connected to a stimulation source.

Regarding claim 29, Maguire et al. disclose the coagulation energy connector(s) and stimulation energy connector define different configurations, as the proximal ends of (104 and/or 102) are distinct from the proximal end of (118), see col. 5:8-34 and figure 3.

Regarding claims 30-32, Maguire et al. disclose a surgical system, comprising: a source of coagulation energy (R-F energy source, see col. 11:36 – 12: 9); and a surgical probe (the totality of the device shown in figure 1), the surgical probe including a relatively short ("catheter body" 10, see col. 3:43-50 and figure 1) defining a distal region and a proximal region, a handle ("control handle" 22, see col. 3:54-60 and figure 1) associated with the proximal region of the relative short shaft, a coagulation element (electrode(s) 12 and/or 16, see col. 3:43-52 and figure 1) configured to emit energy for coagulating tissue and forming a lesion within tissue, the coagulation element defining a coagulation element configuration (coil electrode(s) configuration) on the distal region of the relatively short shaft, and a mapping/stimulating element ("electrode" 20 and "additional mapping electrodes may optionally be added between electrodes 12 and 16 and/or proximal to electrode 12," see col. 3:45-54 and figure 1) configured for mapping tissue and evaluating formation of the lesion, the mapping/stimulation element defining a mapping/stimulation element configuration (cap electrode configuration) on the distal region of the relatively short shaft, the stimulation element configuration being different

than the coagulation element configuration, wherein a coagulation energy connector (proximal ends of 104 and 102 connected to 12 and 16 respectively that are located within "electrical connector" 28 at the proximal end of the "control handle" 22, see col. 3:63-65, col. 5:8-19 and figure 1) is carried by the handle and a stimulation energy line (118, see col. 5:20-38 and figure 3) extends through the handle. Maguire et al. fail to explicitly disclose 1) that the mapping electrodes are configured to emit energy to tissue for stimulating tissue and evaluating formation of the lesion, the stimulation element and 2) a source of stimulation energy. Both Maguire et al. and Leob et al. are silent as to a source of stimulation energy, which the examiner interprets has simply a source operatively coupled to the mapping/stimulation electrodes to deliver energy to the mapping/stimulation electrodes. Leob et al. disclose an electrosurgical device and procedure for forming a channel within tissue and teach "attached to the cannula distal end portion 773 are serially spaced mapping electrode rings 715 for monitoring parts of the body. Such mapping electrodes are known in the art and, for example, provide for electrically mapping the heart by receiving and transmitting electrical signals related to the operation of that organ to recording signal processing and display devices," see col. 15:27-57 and figure 20. Leob et al. disclose that it is known in the art that mapping electrodes not only receive (i.e. sense, detect, etc.) electrical signals but also transmit (i.e. send, deliver, etc.) electrical signals. The transmission of electrical signals through tissue to by the mapping electrodes meets the function of a stimulating element. Dupree et al. disclose a device and method for mapping and ablating tissue and "the techniques used to analyze these pathways, commonly called 'mapping,' identify regions in the heart tissue,

called foci, which can be ablated to treat the arrhythmia. When used for this purpose, the multiple electrode arrays are typically located in electrical contact with either epicardial or endocardial tissue. The multiple electrodes are coupled to an external cardiac stimulator, which applies electrical pacing signals through one or more electrodes at given frequencies, durations, or amplitudes to myocardial tissue, a process called 'pacing.' The multiple electrodes on the array are also typically coupled to signal processing equipment, called 'recorders,' which display the morphologies of the electrocardiograms or electrograms recorded during pacing," see col. 1:23-36. Dupree et al. teach the pacing pulses (delivered to the mapping electrodes) are "generated by the stimulator 20" which is a subsystem of "instrument interface" 26 (i.e. the stimulation source), see col. 8:54-57 and figure 2. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Maguire et al., as taught by Leob et al., to use mapping electrodes, as is known in the art, that both stimulate tissue (transmit electrical signals through tissue) and receive electrical signals (stimuli) in order to map the tissue, as further taught by Dupree et al., to provide the system with a source of stimulation energy operatively coupled to the stimulation/mapping electrodes in order to map the tissue treatment area.

Regarding claim 33, Maguire et al. clearly disclose that the length of a coagulation electrode (either of electrode 12 or 16) is longer than the length of the mapping electrode (20), see figures 1 and 3.

Regarding claim 34, Maguire et al. further disclose at least two longitudinally spaced coagulation electrodes (electrodes 12 and 16, see col. 3:43-52 and figure 1) having a size and spacing. The recitation of "the at least two coagulation electrodes being such that simultaneous transmission of energy thereby to an indifferent electrode will produce an area of coagulated tissue that spans the at least two coagulation electrodes" is intended use. A recitation of intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. However, if a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. Furthermore, the entire disclosure of Maguire et al. is directed to creating elongated lesions.

Regarding claim 36, Maguire et al. in view of Leob et alin further view of Dupree et al. disclose the claimed invention, as the "instrument interface" (i.e. the stimulation source) 26 of Dupree et al. has a "recorder" 22 subsystem for monitoring electrical impulses sensed by the stimulation element, see col. 8:13-19 and figure 2.

Regarding claims 39 and 43, Maguire et al. further disclose the coagulation element (12 and/or 16) and the stimulation element (20) are carried on the same relatively short tubular shaft (10) such that the coagulation element and the stimulation element are longitudinally fixed relative to one another, see figures 1 and 3.

Regarding claims 40 and 44, Maguire et al. further disclose the distal portion of the relatively short tubular shaft (10) includes a unitary outer member ("insulative member" 14, see col. and figure 3) and the coagulation element (12 and/or 16) and the stimulation element (20) are both carried on the unitary outer member, see col. 3:43-56 figures 1 and 3.

Regarding claims 42 and 46, Maguire et al. further disclose the coagulation element (12 and/or 16) and the stimulation element (20) define respective diameters and the diameter of the coagulation element is substantially equal to the diameter of the stimulation element, see figures 1 and 3.

Regarding claim 50, Maguire et al. in view of Leob et al. in view of Dupree et al. disclose the stimulation element, in the form of a mapping electrode (20 of Maguire et al. figures 1 and 3) is located distally of the coagulation element, in the form of ablation/coagulation electrodes 12 and 16, see col. 3:43-52 and figures 1 and 3).

Regarding claims 51-54, Maguire et al. disclose the claimed invention see figure 1. The recited linearity and coaxial nature of the shaft is interpreted as intended use and/or a functional limitation. A recitation of intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim.

However, if a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. It is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, *i.e.*, a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim. In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974); In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 136 USPQ 458 (CCPA 1963). Where the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function. In re Ludtke, 441 F.2d 660, 169 USPQ 563 (CCPA 1971). In addition, where there is reason to believe that such functional limitation may be an inherent characteristic of the prior art reference, Applicant is required to prove that the subject matter shown in the prior art reference does not possess the characteristic relied upon. In re Spada, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990); In re King, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986); In re Ludtke, 441 F.2d at 664, 169 USPQ at 566 (CCPA 1971). As can be clearly seen from figure 1 of Maguire et al., the device is capable of the intended use and/or function.

Claims 8, 35 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maguire et al. (U.S. Patent 5,755,760) in view of Leob et al. (U.S. Patent 6,286,512) in further view of

Dupree et al. (U.S. Patent 6,542,773) as applied to claims 1, 27 and 47 above, and still further in view of Haissaguerre et al. (U.S. Patent 5,931,811).

Regarding claim 35, Maguire et al. in view of Leob et al. in further view of Dupree et al. disclose the claimed invention except for at least a portion of the distal region of the relatively short tubular shaft is malleable. Haissaguerre et al. disclose a catheter having steering capability and electrodes (28) and teach "the distal section 40 is preshaped to generally correspond to the physiology of the tissue to be mapped or ablated, for example, to have a radius corresponding to the radius of the inner wall of the right atrium. The shape may set into the material of the distal section of the shaft 30, or may be imparted to a hypotube 42 (FIG. 3), stiffening wire, or other elongate element capable of taking a set such as an element made of stainless steel or a shape memory alloy such as nickel-titanium. The shape of the distal section 40 is not affected by steering the catheter 20 to its fully steered configuration," see col. 3:35-52 and figures 1-3. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Maguire et al. in view of Leob et al., as taught by Haissaguerre et al., to provide the distal portion of the catheter with shape memory material in the form of nickel-titanium in order to set the shape of the distal portion.

Response to Arguments

Applicant's arguments with respect to claims 1-6, 8-10, 30-33, 47-50 and 54 have been considered but are moot in view of the new ground(s) of rejection. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Due to Applicant's amendment, the Dupree et al. patent was used in combination with Maguire et al. in view of Leob et al. to rejection all of the independent claims and most of the dependent claims.

Applicant's arguments filed on 4/24/2009 with respect to claims 27-29, 34-36, 43, 44, 46 and 52 (see pages 17-18 Argument V.) have been fully considered but they are not persuasive. Applicant's arguments/remarks against the Maguire et al. in view of Leob et al. combination are moot as they do not take into consideration the "pace mapping" taught by Dupree et al. wherein the mapping electrodes send out, transmit electrical stimulation signals through the target tissue to other receiving mapping electrodes. Pace mapping is something extremely well known in the art.

Finally, the recitation of "supplying tissue stimulation energy to a first side of a lesion that is formed as a result of ablating tissue such that a second side of the lesion can be monitored to determine a depth of the lesion" is a recitation of 1) intended use, 2) language directed to how the device/element is intended to be employed and/or 3) a functional limitation. A recitation of intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. However, if a prior art structure is capable of performing the intended

use as recited in the preamble, then it meets the claim. A recitation with respect to the manner in which an apparatus is intended to be employed does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim. In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974); In re Yanush, 477 F.2d 958, 177 USPQ 705 (CCPA 1973); In re Finsterwalder, 436 F.2d 1028, 168 USPQ 530 (CCPA 1971); In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 136 USPQ 458 (CCPA 1963); Ex parte Masham, 2 USPQ2d 1647 (BdPatApp & Inter 1987). It is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, *i.e.*, a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim. In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974); In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 136 USPQ 458 (CCPA 1963). Where the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function. In re Ludtke, 441 F.2d 660, 169 USPQ 563 (CCPA 1971). In addition, where there is reason to believe that such functional limitation may be an inherent characteristic of the prior art reference, Applicant is required to prove that the subject matter shown in the prior art reference does not possess the characteristic relied upon. In re Spada, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990); In re King, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986); In re Ludtke, 441 F.2d at 664, 169 USPQ at 566 (CCPA 1971).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 8:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Aaron Roane/
Examiner, Art Unit 3769

/Ahmed M Farah/
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